

INSTRUCTIONS FOR PREPARATION OF MERIT REVIEW APPLICATIONS

These guidelines were developed to help you prepare a VA Merit Review Application. For additional information you should review the VA Merit Review Program guidelines (M-3, Part II, Chapter 4). All components listed starting with VA Form 10-1313-1 (page 1 of the application) need to be addressed. Contact Steve Breese, Administrative Officer for R&D at extension 7669 or steve-breese@icva.gov concerning eligibility for submission of VA applications and Nancy Spevacek at extension 7645 or spev@icva.gov for the appropriate VA forms (10-1313's, Animal Care and Use Forms and Biohazard Forms). Please call us concerning any questions you may have concerning the VA Merit Review program.

GENERAL INSTRUCTIONS

The local deadline for the June and December submissions are as follows:

- Waiver to perform research off-site – April 1 or October 1
- Letter of Intent for Funding exceeding \$135,000 per year – April 1 or October 1
- Draft for local review -- April 15 or October 15.
- Animal Care and Use forms are due in the Research Office - April 15 or October 15.
- Final proposal including all approvals, must be in the Research Office-June 1 or December 1.

Off-Site Research. Any investigator whose lab is located at the University must discuss research space with Steve Breese (x7669 or steve-breese@icva.gov). Investigators submitting merit reviews must have assigned research space at the VAMC or VA leased space at the University. In the resources section of the narrative reference must be made the where the VA lab is located, including room numbers, and square footage.

Request for funding exceeding \$135,000 per year. Applicants requesting annual budgets exceeding \$135,000 exclusive of equipment and Principal Investigator (Ph.D.) salary costs must submit a Letter of Intent (LOI) prior to proposal submission. Submit the LOI's to the Research Office no later than April 1 or October 1. Guidelines are available from the Research Office (7645).

Narrative. The narrative should be typed in elite style, 12 pitch. Capital letters must be approximately 1/8 inch in height and there may be no more than 15 characters (including spaces) per inch. In addition, there may be no more than six lines of text per vertical inch. Type material single spaced, leaving a 1 inch wide binding margin at the edge of each sheet. If the print is too small reviewers have a difficult time reading, as they usually review six to eight applications. Use plain white paper with a quality printer. **Narrative Length.** The merit review narrative of the proposal is limited to fifteen (15) pages, unless there are two or more distinct projects (five additional pages for additional projects up to a maximum of twenty-five). The narrative begins with the rationale and goes up to the references, but does not include the references. The list of publications resulting from prior funding and figures incorporated into the text instead of the appendix are not counted against the 15 page limit for the narrative.

The signed original only and any manuscripts (seven copies) are needed in the Research Office. We make the 25 extra copies and send them into VA Central Office.

Page numbers. The investigators last name should be typed in the lower right hand corner along with the page number, e.g., Smith - 1. Number each page consecutive starting with 10-1313-1 as page 1 (Smith - 1), through the Director's letter (smith- 34). Appendix should be numbered consecutively starting with appendix - 1 (Smith -Appendix - 1).

Manuscripts. Five reprints or manuscripts may be submitted with each application (submit seven copies of each article to the Research Office).

Photos. Original photos are treated as an additional reprint (submit seven copies of each photo to the Research Office). Original photos should not be incorporated into the narrative unless they are included in all 25 copies of the proposal and they do not count as one of the reprints.

Reviewers. Applicants must submit two or more names of ad hoc reviewers at the time of submission. These individuals should be knowledgeable in the field of research. It should not be someone from Iowa City. Do not contact these individuals to see if they will review the proposal. Please include the name, address, phone number and fax number of the suggested reviewer. Suggested reviewers form on web site.

Forms. VA forms can be completed by either word documents (see web site) or MerPages. MerPages 2.5 for windows is an application that allows you to complete and print pages 10-1313-3 through 10-1313-8 of the merit review forms. System requirements to run the program are; 386 computer, 3.5-inch diskette drive, 8 MB RAM, 5 MB available hard disk space, VGA Monitor, Mouse, Printer (HP Laserjet III and 4 printers) and Windows 3.1x, Windows 95 or Windows 3.5x. Contact the Nancy at extension 7645 for a copy of MerPages.

ALL APPROVALS MUST BE DATED WITHIN 12 MONTHS OF SUBMISSION OF THE APPLICATION.

Human subjects forms are available through the Human Subjects Office at the University website – www.uiowa.edu. The VA block should be checked for VA applications. It takes at least six weeks to get IRB approval. See page 14 for additional human subjects guidelines. VA consent forms 10-1086 must be used for the informed consents.

Approval forms for **Animal Care Studies** (must be in VA format) can be obtained from Sandi Rowe, extension 7672. The forms are due in the Research Office no later than April 15 or October 15. See page 14 for additional Animal Care and Use guidelines.

Biohazard statements and **DNA** registration forms should be submitted to Sandi Rowe for approval by the Biosafety Committee, no later than April 15 or October 15. Any questions should be referred to either Sandi, extension 7672, or Gerene Denning, Ph.D., extension 7573. See page 14 for additional biohazard and DNA guidelines.

A current **laboratory radiation approval** is required if the research involves the use of radioactive materials. Copies of the license should be obtained from the University's Health Protection Office (HPO) if the lab is located at the University or Nuclear Medicine Service if the lab is located at the VAMC. See page 15 for additional guidelines for radiation license.

PROVIDE TITLE OF MERIT REVIEW PROJECT TO THE RESEARCH OFFICE TO COMPLETE VA FORM 10-1313-1

We must submit the computer generated RDIS page of 10-1313-1 with the proposal. This is necessary to make sure what is submitted on the computer system (RDIS) and what is submitted with the merit review are exactly the same. Please provide us with the title of your merit review as soon as possible and we can print the RDIS page 1. This will allow you time to review the data. The majority of the page will be completed, except for the budget and program use information. Please contact Nancy Spevacek at extension 7645 with the title, and a the 10-1313-1 page will be generated.

VA FORM 10-1313-1 - Merit Review Application

Item 1. Leave blank

Item 2. Leave blank

Item 3. Leave blank

Item 4. Leave blank

Item 5. Type in 584

Item 6. Type in VA Medical Center, Iowa City, Iowa

Item 7. Investigator's Social Security Number

Item 8. The last time the investigator submitted a VA Merit Review Application.

Item 9. Type the last name of the investigator in capital letters, followed by the first name and initial of middle name. List degree(s) , and telephone number of investigators office.

Item 10. Title is limited to 72 characters (including spaces). The title should not contain references to animals or specific species, e.g., "in the turkey", "in man."

Item 11. Type in the budget totals from page 10-1313-4.

Item 12. Check current VA employment status. To be eligible for VA funding the investigator needs to be; (1) atleast a 5/8ths VA employee; or (2) have their eligibility approved by VA Central Office prior to submission of MR application.

Item 13. Check the appropriate box for VA salary source. The majority of MD investigators are patient care salaried, and Ph.D. investigators are research cc 103.

Item 14. New is for investigators who currently do not have VA funding.

- Ongoing is for investigators who have VA funding and are sending in a renewal application, or had VA funding in the past five years
- Supplement - Not applicable
- No. Projects in Program - type 1, or type 2 or 3, etc., if program involves more than 1 project

Item 15. Program - type 821
Cost Center - type 103

Item 16. Insert both the primary research program area and primary specialty area that applies to the principal investigator. See RDIS VA Form (attached) 10-5368 for codes, use # 7 for primary research specialty area, and #13 and #14 for primary research program area. The program areas should be the same as those reported on your RDIS page 18.

Item 17. Insert the service the investigator is associated with at the VA Medical Center, e.g., Infectious Diseases, Medical Service.

Item 18. Insert the University of Iowa academic rank, department, and affiliation of the investigator, e.g., Professor, Internal Medicine, College of Medicine, University of Iowa.

Item 19. Mark the items that apply to this application.

- **Human Subjects** - If the project uses human subjects, mark this box. VA Forms 10-1223/10-1086 must be contained in the proposal and be dated within 12 months of submission. See human subjects on page 14 for further details.
- **Animal Subjects** - If animals are used in the project, mark this box. A copy of the current (within 12 months of submission) VA approved animal care forms needs to be included in the proposal. See animal subjects on page 14 for further details. (Contact Sandi Rowe to get animals approved through the VA Animal Care and Use Committee).
- **Investigational Drugs** - If Investigational drugs are used in the project, mark this box. A copy of the current Committee A approval (within 12 months of submission) is needed and should be included with the human subjects information in the proposal.
- **Investigational Devices** - If Investigational devices are used in the project, mark this box. A copy of the current Committee A approval (within 12 months of submission) is needed and should be included with the human subjects information in the proposal.
- **Radioisotopes** - If the project is using any type of radioactivity, mark this box. A current laboratory radiation approval (within one year) needs to be included in the proposal. If the lab is at the University, a license can be obtained from University Health Protection Office (HPO); if the lab is at the VA, the license is issued by Nuclear Medicine Service. See radiation requirements on page 15 for further details.
- **Biohazards** - If the project is using any type of biohazards, mark this box. A current approval (within one year) is needed to be included in the proposal. Biohazards include; DNA, Recombinant DNA, carcinogens, infectious diseases, such as TB. See biohazards requirements on page 15 for further details.

Item 20. This section is for totals in research funding for the past three years. For example, if this is fiscal year (FY) 1997, the last three years are 1996, 1995 and 1994. A fiscal year is

October 1 through September 30. For the totals of VA research funding call the Research Office for the amounts. Totals of Non-VA funding is all other funding received by the investigator. The grand total is the total of both VA and non-VA columns.

Item 21. This is the date the investigator started working for the VA , or the date he/she is expected to start employment at the VA.

The form need to be signed and dated by the investigator.

VA FORM 10-1313-2 - Summary Description of Program/Project

- At the top of the page mark the program box, very rarely is project marked.
- Type in applicants name.
- Type in title of program.
- List key words that best describe the scientific disciplines encompassed by the studies.
- The abstract should include the research program objective(s), hypotheses and procedures, but do not include technical details.

These forms can be generated by Word documents or MerPages. Contact Research (x-7645) for a copy of MerPages - Word Documents on Web Site.

VA FORM 10-1313-3 - Current Funds and First Year Request

- Budget limit of \$135,000 per year, see note on bottom of page.
- At the top of the page mark the program box, very rarely is project marked.
- If there is more than one project involved in program, then a budget sheet needs to be completed for each project and one for total program.
- Type in applicants name.
- Type in title of program.
- Current year funds are for renewal applications only. Current year funds may be obtained from the Research Office. First year requested funds are the funds requested for the first year of the proposal.

Note: Round dollars to the nearest \$100.

Personnel budget. List all personnel involved in the proposal, including the investigator. Give their names, GS grade levels and job titles. List the percent they will work on the project. List salaries, including fringe benefits (35%) for all personnel. Justification of the employees should be documented on page 10-1313-4. This will include what they will do, and what expertise they bring to the proposal. Secretarial salaries are not allowed. Contact the Research Office (x7645 for current pay scale).

Consultant Services. List each consultant and their cost. On page 10-1313-4 justify the nature of the service to be performed. Append to the proposal a letter from each individual agreeing to consult, along with details of the nature of the consultations. There are limitations on how much a consultant can be paid. Call the Research Office for details. Mer Pages will not accept \$0 amount. This needs to be typed in with a typewriter.

Data Management. You should consider the amount of resources that is needed to complete this section of your research application. You may want to hire a Data Analyst or use consultation services to pay for data and statistical services.

Equipment. List each item of equipment to be purchased. Provide a justification on page 10-1313-4 for equipment over \$3,000. For major equipment items, indicate how many similar instruments are located at the facility and in nearby laboratories. Total the equipment request at the bottom of the section.

Computers. You should include a computer on the equipment budget of all new or renewal applications. Approximately \$3,500 should cover the cost of computer, monitor and laser printer. It appears that over a five year research plan, computers need to be upgraded or replaced. List computers as an equipment item.

Supplies. List supplies by major types such as glassware, chemicals, isotopes, etc. Total the supplies requested at the bottom of the section.

All Other Expenses. List all other expenses by major category, including costs for photocopies, graphics, publications, manuscript fees, and animals (type and number, their unit costs and unit care costs). **Computer Network Services** should also be included in all applications. **Do not include travel to conferences.** Total the other expenses requested at the bottom of the section.

- Total Operating Expenses are the totals of all the sections.

Budgets over \$135,000 per year (Excluding principal investigator salary (Ph.D) and first year equipment must obtain prior approval from VACO. A Letter of Intent (LOI) must be submitted to the Research Office by April 1 or October 1. Call the Research Office (7645) for guidelines.

These forms can be generated by Word documents or MerPages. Contact Research (x-7645) for a copy of MerPages - Word Documents on Web Site.

VA FORM 10-1313-4 - Estimated Expenses

- At the top of the page mark the program box, very rarely is project marked.

\$Amount Each Year - The 1st section is the same figure that appears on page 10-1313-3. The sections on 2nd, 3rd, 4th, and 5th are the budget figures for the subsequent years.

- **Note:** Round dollars to the nearest \$100.
- **Note:** Do not include inflationary increases in any of the budget categories and do not include cost-of-living increases. All the columns across the page should be the same, any differences must be explained in the next section. (If you want to include cost of living, it must be reflected in year one through project completion.)

Explain Differences. Explain any differences in the figures from year to year, e.g., equipment purchased in first year only.

Justification of Items Page 3. This is the section where you justify the budget items from page 10-1313-3. You can use plain white paper to continue the justification if needed.

- **Note** - If you are hiring or paying a collaborator with specific expertise needed to complete the study, make sure to emphasize the qualifications in the justification.

These forms can be generated by Word documents or MerPages. Contact Research (x-7645) for a copy of MerPages - Word Documents on Web Site.

VA FORM - 10-1313-5 - Investigator's Biographic Sketch

- **Note:** Biographic sketch forms (10-1313-5, 6, 7 and 8) must be completed for the principal investigator and for each investigator and collaborator who plan to devote more than 5 percent research effort. Include only a biographic sketch for those devoting 5 percent effort or less (10-1313-5 and 6). Do not include any of the above forms for consultants, but include all persons who will participate in the design, performance, and professional direction of the proposed research.

Role in Program. List role in the proposal that the person has who is completing this form, e.g., principal investigator, collaborator, etc.

Education. List the name, location of institution, degree, and year awarded, beginning with baccalaureate. Include post-doctoral training, do not include honorary degree.

Major Research Interest. List research interest of person completing the form.

Research and/or Professional Experience. List in order from present appointment, job experiences, listing dates, titles, and location of experience. **Make sure to list VA appointment.**

Honors and Awards. List honors and awards received.

These forms can be generated by Word documents or MerPages. Contact Research (x-7645) for a copy of MerPages - Word Documents on Web Site.

VA FORM 10-1313-6 - Investigator Bibliography

- **Note:** Do not exceed two pages for each investigator.
- Include a chronological list of all of the most important and pertinent publications, but do not include abstracts, submitted papers, or papers in preparation.
- Literature citations must include the full title of the paper being referenced.
- Do not include curriculum vitae, either in addition to, or in place of, VA Forms 10-1313-5 and 6.

These forms can be generated by Word documents or MerPages. Contact Research (x-7645) for a copy of MerPages - Word Documents on Web Site.

-7 - Total VA and Non-VA Research /Development Support

Page seven is designed to show the investigators current and pending research activities.

- List participants name in the top left corner box.
- **The boxes reading across the top are as follows:**
 - Agency** - list the agency who is funding the research. You can use abbreviations, such as NIH.
 - Grant Number** - The number the agency has given the project.
 - % Effort** - This is the percentage of time the investigator is working on the project.
 - Personnel** - List personnel costs budgeted for the current year.
 - Equipment** - List any equipment costs budgeted for the current year.
 - All Other Expenses** - List other expenses budgeted for the current year.
 - Total Current Year.** List the totals of the costs in the personnel, equipment and all other expenses sections for the project.
 - Total Period Inclusive** - List the dates the projects are funded, e.g., 1/1/92 - 12/31/95.
- **The boxes reading across the side are as follows.**
 - VA** - Current projects funded by the Department of Veterans Affairs. List the Merit Review as MR, and a Career Award as AI (Associate Investigator), RA (Research Associate), and CI (Clinical Investigator).
 - Active Non-Government** - Current projects funded by private agencies, such as drug companies, and foundations.
 - Active Government** - Current projects funded by government agencies (excluding VA), such as NIH.
 - Pending VA and Non-VA** - List all pending applications for all funding sources. Also, list this project as pending. List the Merit Review as MR, and a Career Award as AI (Associate Investigator), RA (Research Associate), and CI (Clinical Investigator).
 - Totals** - Total the columns for % Effort. (**Note:** The percent effort should not exceed 100%, or you need to explain on pages 10-1313-8 how the percentages will be adjusted).
- Do not type in the shaded areas (total current year for pending VA and Non-VA, and totals for personnel, equipment and all other expenses).

NOTE - 10-1313-8 MUST BE COMPLETED

- any project listed on page 10-1313-7 must be addressed on page 10-1313-8.

These forms can be generated by Word documents or MerPages. Contact Research (x-7645) for a copy of MerPages - Word Documents on Web Site.

VA FORM 10-1313-8 - Investigator's Total VA and Non-VA Research/Development Support

Name - List participant's name

Status - Insert one of the following VA(VA); G (government); NG (non-government); P (pending).

Grant Project No. - Use the project number listed on page 10-1313-7.

Grant/Project Title - List title of project.

Abstract - Discuss fully every funded or pending project listed on VA Form 10-1313-7. A brief summary of the project needs to be addressed in this section. Include duration of support and total funding level and a brief statement of what the project involves. The relationship to the proposal being submitted should be addressed as well as any overlap, financially and scientifically. In case of overlap, you need to say what you will do if both are funded. A statement such as "significant scientific overlap exists between the NIH R01 and the VA Merit Review. If both are funded, the amounts accepted would be negotiated at the time of funding." If there is no overlap, add the statement "there are no budgetary, scientific, or administrative overlaps."

NOTE - ABSTRACTS AND BUDGET PAGES NEEDED.

The budget and summary abstract pages from all non-VA projects listed on pages 10-1313-7 and 8 must be inserted after the form page 10-1313-8 (excluding current application).

Resubmission Letter

Investigators resubmitting an application that did not get funding must include a letter after VA form 10-1313-8 (abstracts and budget pages) no longer than three pages, indicating how and where responses to the last review have been addressed. If you are changing the entire project from the previously submitted application, include a statement explaining why the change in focus. Revised applications with no substantial revisions and no response to previous critiques often receive an unfavorable review. Amended applications that do not include this letter will be returned unreviewed.

Abbreviations - Include a list of abbreviations used in the proposal.

NARRATIVE

Include sufficient information to facilitate an effective review without reference to any previous application. Brevity and clarity are essential components in the presentation of a research plan. There is a 15-page limit on the narrative portion of merit review applications. In complex programs with diverse projects, each of which must have a separate budget, the narrative may extend up to 5 pages for each additional project to a total of not more than 25 pages. **The list of publications resulting from prior funding and figures incorporated into the text instead of the appendix are not counted against the 15 page limit for narrative.** An appendix describing new, unusual, or unpublished methodology may be added; however, the appendix may not exceed 15 pages and may not be used to expand the narrative. The literature citations, as well as the human consent forms and animal component information forms are not counted toward the 15-page limit of the narrative. Use the following format:

Rationale

Briefly state the problem to be investigated.

State the hypotheses or key questions to be answered by the study.

Summarize specific objectives. Briefly and concisely list the short-term and long-term objectives of this research: for long-term objectives identify expected intermediate goals. Outline an anticipated timetable for achievement of the short-term objectives.

State the current status of research in the area. Describe the research that has been done toward solution of the problem(s) and how this knowledge relates to the hypotheses, or questions presented above. This description should be sufficiently complete to demonstrate that the principal investigator is aware of all related work. When pertinent, studies both supportive of and contrary to the hypotheses should be quoted and discussed. This discussion should be concise and relevant to the problem(s), hypotheses, or questions.

State the significance of this research. Explain the potential importance of the proposed work, and identify any unique ideas or potential contributions that might result from the study. Significance relates to the likelihood that the research will lead to new knowledge or advances within its field of science, when judged by the “current state of art” of the field of science. This is a judgment of the inherent value of the research.

Indicate the relevance of the proposed work to VA patient care mission.

Background and work accomplished.

Describe briefly any studies you and your co-workers have done that are pertinent to this proposal. If this is an ongoing program or a request for supplemental funds, include a detailed report of the progress made since the program's inception. The Progress Report should describe accomplishments to date and may include charts, graphs, or other materials that succinctly present significant data. If progress can be best described by some of your publications, submit six copies of each pertinent paper (up to five) to support your Progress Report.

Work Proposed

Methods of procedure. Give details of your research plan, including descriptive examples of the types of experiments or other work that you propose, the major methods to be used, the specific techniques (e.g., instrumentation, statistical methods) to be employed, the kinds of data that you expect to obtain, and the means by which the data will be analyzed and interpreted. Be as specific as possible. When animals are to be used, list the number and types, including strains and species.

Resources.

Describe the VA facilities (including VA leased space at the University) and personnel required for the projects. Indicate which are available and which must be obtained, including office and laboratory space, data processing facilities, clinical research facilities, access to specific patients, access to VA staff, animal rooms, and major equipment and/or supply items. Include room numbers and square footage. Contact Steve Breese (x7669 or steve-breese@icva.gov) regarding VA space.

Collaboration.

Describe any proposed collaboration with institutions and investigators. Include a description of the role of additional professional personnel and a letter from each agreeing to participate. A biosketch (limited to two pages) on collaborators may be included if you need to show the collaborators expertise.

Publications.

List all your major publications resulting from work done during the period on which you are reporting. Do not include clinical case reports, summaries, or verbatim records of lectures, review articles, or abstracts of papers presented at meetings.

Literature references.

Include full titles of each published paper cited. Limit this information to a maximum of four pages.

Safety Checklist.

Complete the safety checklist. If yes is marked in any of the columns, the appropriate forms needs to be included with the checklist. If examples of biohazard statements are needed please call Sandi Rowe (x7672) or Nancy Spevacek (x7645) in the Research Office. Safety checklist provided on Web Site.

High Hazardous Chemicals

If any of the highly hazardous chemicals listed in the safety checklist packet are being used page 3 of the safety packet needs to be completed. You can list "Per MSDS" in the Safety Precautions/Disposal section.

Microbial Agents

If you are using any microbial agents in the proposal, you need to complete microorganism page in the safety checklist packet.

Human Cell Lines/Tissue/Material (Bone etc.)

If you are using human cell lines/tissue/material (bone etc.) in the proposal, you need to complete the human cell line/tissue/material (bone etc.) page in the safety checklist packet.

Containment Equipment

If you are using any containment equipment in the proposal, such as a biological safety hood, you need to complete the containment equipment page in the safety checklist packet. Make sure to list the date of last certification for biological safety hoods.

VA Form 10-1223, Report of Subcommittee on Human Studies.

Approval forms for human use studies need to be current (within 12 months of submission). **The title on the approval form (VA Form 10-1223) and the consent forms need to match the title of the application.** Forms are available from University of Iowa – Human Subjects web page. It is the University Human Use Committee that reviews the applications. The VA block should be checked for VA applications. We are now required to use the VA Research Consent Forms (10-1086) forms are available on the University web site. It takes at least six weeks to get IRB approval. If the titles are different, submit a letter of justification to the Research Office (no later than June 1 or December 1). Prior approval from VA Central Office is needed. Any questions concerning human subjects should be addressed to Human Subjects Office or Nancy Spevacek (extension 7645) in the Research Office.

Human Subjects Educational Requirement. Each proposal involving human studies must document successful completion of the human subjects training requirement by the Principal Investigator, Co-Principal Investigators, and Co-Investigators participating in the project. Documentation may be in the form of a certificate from the training program for each investigator. Contact Nancy Spevacek (x-7645) for further information on training.

Animal Component of Research Protocol Statement.

All research involving the use of animals must contain approval from the Iowa City VA Medical Center Animal Care and Use Committee. The VA uses its own format and copies of the forms, are available on web site or from Sandi Rowe (extension 7672) in the Research Office. The Animal Care and Use Committee requires that all forms be submitted by April 15 or October 15. This allows the Committee time to review and corrections processed before the final proposal deadline dates. It is very rare for a proposal to be approved the first time. Make sure the dates on the approval are current (within 12 months of submission). **The title of the animal forms needs to match the title of the application.**

Laboratory Radiation Approval.

Any proposal that is planning on using radioactive material must provide proof that their labs are currently approved for such use. A copy of the current (within 12 months of submission) laboratory radiation approval is needed. A copy of the approval should be obtained from the Health Protection Office (HPO) for labs located at the University and the Nuclear Medicine Service for labs at the VA. Make sure the dates on the license have not expired.

Biohazard Statement.

Proposals containing procedures that constitute a potential or possible biohazard must be accompanied by a current explanation of safety precautions to be taken. A signed and dated statement of the local VA or University Biohazard Committee on Safety must be submitted with the proposal (dated within 12 months of submission). A biohazard would include, Recombinant DNA, known carcinogens, infectious diseases, (e.g., TB), or using any human tissue, (e.g., blood, urine, human cell lines). Approval forms are available in the Research Office, contact either Sandi Rowe (x7672) or Nancy Spevacek (x7645).

Letters of Endorsement (Formal letters are required.).

- Letters are needed from participating or effected organizations, for example; other VAMC's, or University Departments.
- Letters are needed from each individual named as a consultant or collaborator explaining their contributions and commitment to the proposal. If the consultant or collaborator has a VA appointment, make sure the endorsement letter is on VA letterhead.

R&D Committee Review of Proposal

Completed by the Research Office.

VA Medical Center Letter

Director letter is completed by the Research Office

Appendix

An appendix may be added to include figures, charts and special methodology and is limited to fifteen (15) pages. Do not use the appendix to expand the narrative.

Manuscripts. Five reprints or manuscripts may be submitted with each application (submit seven copies of each article to the Research Office).

Photos. Original photos are treated as an additional reprint (submit seven copies of each photo to the Research Office). Original photos should not be incorporated into the narrative unless they are included in all 25 copies of the proposal and they do not count as one of the reprints.

Reviewers. Applicants must submit two or more names of ad hoc reviewers at the time of submission. These individuals should be knowledgeable in the field of research. It should not be someone from Iowa City. Do not contact these individuals to see if they will review the proposal. Please include the name, address, phone number and fax number of the suggested reviewer.

Medical Research Service Portfolio Form. Complete and sign the form incuded on web site.

CHECKLIST

_____ Type material single space, elite type, 1 inch margins

_____ PI's name in lower right portion of each page

_____ Page number consecutive

_____ 10-1313-1

_____ Title 72 characters

_____ Figures same as 10-1313-4

_____ Program use (#19) include appropriate approval documents

_____ PI's signature

_____ 10-1313-2

_____ Check appropriate box (Program)

_____ 10-1313-3

_____ Check appropriate box (Program)

_____ List salaries including fringe benefits (35%)

_____ Round off dollars to nearest \$100

_____ List consultants - include agreement to participate letter

_____ Equipment - justify items over \$3,000 on page 4

_____ Animals & radionuclides purchases include appropriate approvals documents

_____ 10-1313-4

_____ Check appropriate box (Program)

_____ Total of first year cost identical to 10-1313-3

_____ All costs should be the same across the years (justify any differences)

_____ Justify equipment over \$3,000

All bibliography forms (10-1313-5/6/7/8) needs to be completed for investigators & collaborators who plan to devote more than 5% effort and forms 10-1313-5/6 for less than 5% effort.

_____ 10-1313-5

_____ List VA appointment

_____ 10-1313-6

_____ Bibliography should not exceed two pages

_____ 10-1313-7

_____ Include pending request (include this project as pending)

_____ 10-1313-8

_____ Every project listed on 10-1313-7 must be discussed on page 10-1313-8

_____ Address scientific or budget overlap issues

_____ Include abstracts & budget pages of non-VA grants list on pages 10-1313-7/8

- _____ Resubmission letter if applicable (3 page limit)
- _____ List of Abbreviations
- _____ Narrative (15 page limit)
- _____ Literature References (4 page limit)
- _____ Safety Checklist
 - _____ Microbial Agents
 - _____ Chemicals (highly hazardous chemicals)
 - _____ Biohazard Statement (human tissue)
 - _____ Human Cell Lines/Tissue /Material (Bone etc.)
 - _____ Containment Equipment
- _____ Human subject approval
 - _____ VA form 10-1223 including the information summary & basic consent forms
 - _____ Title on consents and 10-1223 same as merit review application
 - _____ Approved within year
- _____ Documentation of Human Subjects Training.
- _____ Animal care and use forms
 - _____ Original VA forms - signed
 - _____ Title same as merit review application
 - _____ Approved within year
- _____ Laboratory radiation approval
 - _____ Approved with year
- _____ Biohazards/DNA
 - _____ UI labs need Dr. Kirchhoff's signature/ VA labs needs Gerene Denning signature
 - _____ Approval within year
- _____ Consultants letters
 - _____ Letter agreeing to participate - include biosketch if appropriate
- _____ VA letters (Research Office will incorporate into grant)
- _____ Appendix
 - _____ Not to exceed 15 pages
- _____ Manuscripts/Reprints - 7 copies of up to 5 papers
- _____ Photo's - 7 copies
- _____ Suggested reviewers (form on web site)
- _____ Medical Research Service Portfolio Form (form on web site)

7. **SPECIALTY:** Select Board or area of training or expertise. If 99 is selected, enter name in space provided.

01 = Allergy & Immunology	70 = Emergency Medicine	34 = Nursing	51 = Physiology
66 = Anatomic Pathology	16 = Endodontics	35 = ObstetriGs/Gynecology	52 = Plastic Surgery
67 = Anatomic & Clinical Pathology Medicine	17 = Engineering	71 = Occupational Medicine	53 = Preventive
02 = Anatomy	18 = Epidemiology	36 = Oncology	54 = Public Health
03 = Anesthesiology	19 = Family Practice	37 = Operations Research	55 = Prosthodontics
04 = Anthropology	20 = General Practice	38 = Ophthalmology	56 = Psychiatry
05 = Audiology	21 = Genetics	39 = Optometry	57 = Psychology
06 = Biochemistry	22 = Geriatrics	40 = Oral Pathology	73 = Radiation
Oncology			
07 = Bioengineering	23 = Health Care Administration	41 = Oral Surgery	58 = Radiology
08 = Biology	24 = Health Economics	42 = Orthopedic Surgery	59 = Rehabilitative
Medicine			
09 = Biophysics	25 = Histology	43 = Osteopathy	60 = Social Work
10 = Biostatistics	26 = Immunology	44 = Otolaryngology	61 = Sociology
11 = Chemistry	27 = Internal Medicine	45 = Pathology	62 = Speech
Pathology			
68 = Clinical Pathology (General)	28 = Mathematics	46 = Pediatrics	63 = Surgery
12 = Colon & Rectal Surgery	29 = Medical Illustration	47 = Periodontics	64 = Thoracic
Surgery			
13 = Dentistry (General)	30 = Microbiology	48 = Pharmacology	65 = Urology
14 = Dermatology	31 = Neurological Surgery	49 = Pharmacy	99 = Other (Specify)
69 = Diagnostic Radiology	32 = Neurology	72 = Physical Medicine & Rehabilitation	
15 = Dietetics	33 = Nuclear Medicine	50 = Physics	

13 and 14. **PRIMARY and SECONDARY RESEARCH INTERESTS:** Select codes that best define general areas of primary and secondary interests. Do NOT use 00 for primary research interest.

01 = Aging	11 = Drug Dependence	52 = Neuropsychology	29 = Radiology
02 = Alcoholism	45 = Emergency Medicine	21 = Nuclear Medicine & Radiation	61 = Rehabilitation
38 = Ambulatory Care	12 = Endocrinology & Metabolism	22 = Nutrition	30 = Rehabilitative
Medicine			
03 = Anesthesiology	46 = Epidemiology	23 = Nursing	31 = Respiration &
Pulmonary			
Disease			
04 = Audiology & Speech Pathology	13 = Gastroenterology	24 = Oral Biology	32 = Rheurnatology
05 = Basic Sciences	47 = Geriatrics	25 = Oncology	33 = Social Work
06 = Behavioral Sciences	48 = Health Care	53 = Ophthalmology	62 = Spinal Cord
Injuries			
07 = Biochemistry	49 = Health Economics	26 = Orthopedic Surgery	34 = Surgery
39 = Bioengineering	50 = Health Services	27 = Pathology	63 = Urology
40 = Biomechanics	14 = Hematology	54 = Pharmacology	64 = Vascular
Surgery			
08 = Cardiovascular Disorders	15 = Immunology	55 = Pharmacy	35 = Veterinary
Medicine			
41 = Clinical Epidemiology	16 = Infectious Diseases	28 = Podiatry	36 = Virology
09 = Clinical Pharmacology	51 = Medical Education	56 = Post Traumatic Stress Disorders	37 = Vision
42 = Computer Science	17 = Mental Health	57 = Preventive Medicine	99 = Other (Specify)
43 = Critical Care	18 = Molecular Biology	58 = Prostatic Disease	00 = None
44 = Dental Implants	19 = Nephrology	59 = Prosthetics	
10 = Dermatology	20 = Neurology & Neurobiology	60 = Psychiatry	

Revised. January 1997